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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/948,149	10/09/1997	BRIAN M. FENDLY	P1053R2	6683

24510 7590 07/16/2002

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EXAMINER	
SWARTZ, RODNEY P	
ART UNIT	**PAPER NUMBER**
1645	30

DATE MAILED: 07/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/948,149	FENDLY ET AL.	
	Examiner	Art Unit	
	Rodney P. Swartz, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24April2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-40 and 42-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-40, 42-62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 24April2002 has been entered.

Claims 28, 32, 34, 42, and 58 have been amended. New claims 59-62 have been added.

2. Currently, claims 28-40 and 42-62 are pending and under consideration.

Rejections Withdrawn

3. The rejection of claims 28-39 and 42-58 under 35 U.S.C. 112, first paragraph, scope of enablement for all other antibodies, is withdrawn in light of the claim amendments.

Rejections Maintained

4. The rejection of claims 28-31, 37-38, 40, 56, and 57 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Shepard et al (*J. Clin. Immunol.*, 11(3):117-127, 1991) is maintained for reasons put forth in the original rejection.

Applicants argue that Shepard et al is not enabling for the monoclonal antibodies and that the monoclonal antibodies were not publicly available at the time of filing of the instant application.

The examiner has considered applicants' argument, but does not find it persuasive because the argument concerning public availability is not persuasive. There is no Declaration

from Genentech stating public availibility or lack thereof. In addition, applicants' argument states that the antibodies appear to be actually available to the public, just that there may be some restrictions on their use, i.e., a Material Transfer Agreement.

Applicants argue that monoclonal antibody 4D5 was the most potent for inhibiting growth of breast and ovarian tumor cells overexpressing $p185^{HER2}$, while 7C2 nd 7F3 were less active. Thus one of skill in the art would not have been motivated to use 7C2 and 7F3 or antibodies which bind to their epitope.

The examiner has considered applicants' argument, but does not find it persuasive because while 4D5 may exhibit better activity, Shepard et al does teach that the claimed antibodies also exhibit the required activity.

5. The rejection of claims 28-31, 37-38 and 40 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lewis et al (*Cancer Immunol. Immunother.*, 37:255-263, 1993) is maintained for reasons put forth in the original rejection.

Applicants argue that Lewis et al is not enabling for the monoclonal antibodies and that the monoclonal antibodies were not publicly available at the time of filing of the instant application.

The examiner has considered applicants' argument, but does not find it persuasive because the argument concerning public availability is not persuasive. There is no Declaration from Genentech stating public availibility or lack thereof. In addition, applicants' argument

states that the antibodies appear to be actually available to the public, just that there may be some restrictions on their use, i.e., a Material Transfer Agreement.

Applicants argue that monoclonal antibody 4D5 was the most potent for inhibiting growth SK-BR-3 cells, while 7C2 nd 7F3 were less active. Thus one of skill in the art would not have been motivated to use 7C2 and 7F3 or antibodies which bind to their epitope.

The examiner has considered applicants' argument, but does not find it persuasive because while 4D5 may exhibit better activity, Lewis et al does teach that the claimed antibodies also exhibit the required activity.

6. The rejection of claims 32-36, 39, and 58 under 35 U.S.C. 103(a) as being unpatentable Shepard et al (*J. Clin. Immunol.*, 11(3):117-127, 1991), or Lewis et al (*Cancer Immunol. Immunother.*, 37:255-263, 1993), in view of Fendly et al (*Cancer Research*, 50:1550-1558, 1990), Deshane et al (*J. Invest. Med.*, 43(Suppl 2):328A, 1995), and further in view of Senter et al (U.S. Pat. No. 4,975,278) is maintained for reasons put forth in the original rejection.

Applicants argue that Lewis et al and Shepard et al are not enabling for the monoclonal antibodies and that the monoclonal antibodies were not publicly available at the time of filing of the instant application.

The examiner has considered applicants' argument, but does not find it persuasive because the argument concerning public availability is not persuasive. There is no Declaration from Genentech stating public availibility or lack thereof. In addition, applicants' argument

states that the antibodies appear to be actually available to the public, just that there may be some restrictions on their use, i.e., a Material Transfer Agreement.

Applicants argue that monoclonal antibody 4D5 was the most potent for inhibiting growth SK-BR-3 cells or breast and ovarian tumor cells overexpressing $p185^{HER2}$, while 7C2 nd 7F3 were less active. Thus one of skill in the art would not have been motivated to use 7C2 and 7F3 or antibodies which bind to their epitope.

The examiner has considered applicants' argument, but does not find it persuasive because while 4D5 may exhibit better activity, both Shepard et al and Lewis et al does teach that the claimed antibodies also exhibit the required activity.

Applicants argue that Fendly et al, Deshane et al, and Senter et al do not make up for the deficiencies of Shepard et al or Lewis et al.

The examiner has considered applicants' argument but does not find it persuasive. The references, Fendly et al, Deshane et al, and Senter et al, are utilized to teach the production and characterization of the monoclonal antibodies used by Shepard et al and Lewis et al, and provide further motiviation and methodology for eradication of tumor targets by induction of apoptosis.

7. The rejection of claims 42-55 and now new claims 59-62 under 35 U.S.C. 103(a) as being unpatentable Shepard et al (*J. Clin. Immunol.*, 11(3):117-127, 1991), in view of Lewis et al (*Cancer Immunol. Immunother.*, 37:255-263, 1993) and Fendly et al (*Cancer Research*, 50:1550-1558, 1990), and further in view of Deshane et al (*J. Invest. Med.*, 43(Suppl 2):328A, 1995) and Senter et al (U.S. Pat. No. 4,975,278) is maintained for reasons put forth in the original rejection.

The newly added claims 59-62 would have been rejected with claim 42 as put forth by the original rejection of claim 42. Therefore, claims 59-62 are included in the rejection.

Applicants argue that Lewis et al and Shepard et al are not enabling for the monoclonal antibodies and that the monoclonal antibodies were not publicly available at the time of filing of the instant application.

The examiner has considered applicants' argument, but does not find it persuasive because the argument concerning public availability is not persuasive. There is no Declaration from Genentech stating public availibility or lack thereof. In addition, applicants' argument states that the antibodies appear to be actually available to the public, just that there may be some restrictions on their use, i.e., a Material Transfer Agreement.

Applicants argue that monoclonal antibody 4D5 was the most potent for inhibiting growth SK-BR-3 cells or breast and ovarian tumor cells overexpressing $p185^{HER2}$, while 7C2 nd 7F3 were less active. Thus one of skill in the art would not have been motivated to use 7C2 and 7F3 or antibodies which bind to their epitope.

The examiner has considered applicants' argument, but does not find it persuasive because while 4D5 may exhibit better activity, both Shepard et al and Lewis et al does teach that the claimed antibodies also exhibit the required activity.

Applicants argue that Fendly et al, Deshane et al, and Senter et al do not make up for the deficiencies of Shepard et al or Lewis et al.

The examiner has considered applicants' argument but does not find it persuasive. The references, Fendly et al, Deshane et al, and Senter et al, are utilized to teach the production and characterization of the monoclonal antibodies used by Shepard et al and Lewis et al, and provide further motiviation and methodology for eradication of tumor targets by induction of apoptosis.

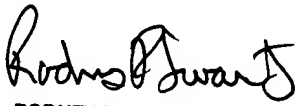
Conclusion

8. No claims are allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (703) 308-4244. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (703)308-3909. The facsimile telephone number for the Art Unit Group is (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-0196.



RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER
Art Unit 1645

July 14, 2002